

## REMARKS

The status of the application is as follows.

Original Claims 1-23 were presented for prosecution.

Original Claims 9-23 were withdrawn from consideration as being non-elected.

Claims 1-8 were previously amended and presently remain pending for consideration by the Examiner.

Claims 1-3, 5 and 6 are further amended herein.

The Examiner rejected Claims 1-3, 5-7 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for non-human mammals allegedly did not reasonably provide enablement for any transgenic, genetically-modified, or cloned animals.

The Examiner rejected Claims 1-8 under 35 U.S.C. 112, second paragraph, as allegedly failing to set forth the subject matter which applicant regarded as his invention, as regards the use of the words, "substantially" and "normal."

The Examiner rejected Claims 1, 2, 4, 5, 7, 8 under 35 U.S.C. § 102(b) as being allegedly anticipated by Young et al., 1984, The American Journal of Clinical Nutrition, 40. 293-302 (hereinafter "Young, et al."), under the doctrine of inherency

Applicant respectfully replies to the Examiner's 35 U.S.C. § 112 first paragraph, 35 U.S.C. § 112 second paragraph, and 35 U.S.C. § 102(b) rejections, and requests continued examination and reconsideration in light of the foregoing amendments and accompanying remarks that follow. In view of the amendments herein, applicant respectfully submits that all of the pending claims are allowable over the prior art of record.

## REMARKS RESPONSIVE TO 35 U.S.C. § 112 FIRST PARAGRAPH REJECTION

The Examiner rejected Claims 1-3, 5-7 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for non-human mammals having a gastrointestinal system, wherein surgery reduced the volume and digestive area of the gastrointestinal tract and results in permanent reduction of preoperative weight, did not reasonably provide enablement for any transgenic, genetically-modified, or cloned animals having a gastrointestinal system, wherein surgery [upon them] reduces the volume and digestive are of the gastrointestinal tract and results in permanent reduction of preoperative weight.

[DETAILED ACTION: PAGE 3, 2<sup>nd</sup> FULL PARAGRAPH]

In response, the applicant has, without adding any new matter, amended both the specification and the claims to clearly limit the use of transgenic, genetically-modified, or cloned animals to such transgenic, genetically-modified, or cloned animals as are *already in existence* at the time that they are selected for the surgical modification productive of the animal model claimed herein, and consequently need not be created by one of ordinary skill in the art in order to serve as candidates for the surgical modification productive of the animal model claimed herein.

## REMARKS RESPONSIVE TO 35 U.S.C. § 112 SECOND PARAGRAPH REJECTION

The Examiner rejected Claims 1-8 under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant regarded as his invention, as regards the use of the words, "substantially" and "normal."

In response, the applicant has deleted the adjective “substantially” as a modifier of the descriptor “normal” everywhere that the adjective “substantially” modified the descriptor “normal” throughout the Original Specification.

The Examiner has acknowledged that “[w]hile the Applicant has referred the Examiner to the specification to indicate what is meant by ‘normal,’ the problem with using ‘normal’ is that it is not clear what metes and bounds are used to describe the other different characteristics of a stomach which could still be considered ‘normal’.” [DETAILED ACTION: PAGE 5, LAST FULL PARAGRAPH]

The paragraph in the Original Specification to which the Examiner was referred, as amended, now reads:

“[T]here is shown in FIG. 1 a schematic illustration of a portion of a ~~substantially~~ normal gastrointestinal tract 48 of an animal, beginning at the terminal esophagus 21 and extending to the mid-jejunum 49. Normal gastrointestinal tract 48 is characterized by several anatomical landmarks and regions. Gastroesophageal junction 26 admits food into the stomach 23, having an apical portion 22, called the fundus, and having a contour with a lesser curvature 24 and a greater curvature 25. Partially digested food passes from the pylorus 28 of the stomach into the duodenum 29, the first division of the small intestine, about 25 cm in length, and thence into the jejunum 33, shown as extending to its approximate midpoint 49.” (Emphasis supplied)

Applicant respectfully submits that the foregoing characterization of a “normal gastrointestinal tract” now establishes clear metes and bounds for the selection of nonhuman mammalian animals as candidates for the surgical modification productive of the claimed animal model. Nonhuman mammalian animals whose gastrointestinal tracts are characterized by the foregoing quoted anatomical landmarks and regions have a “normal” gastrointestinal tract, that is adequate to qualify them as candidates for the surgical modification productive of

the claimed animal model; and, those that do not have the foregoing quoted anatomical landmarks and regions do not have a normal gastrointestinal tract.

While it is hoped that the use of the animal model claimed herein will have value for human medicine, the clinical standard of “normal” required to select a nonhuman mammalian animal for surgical modification into the claimed animal model merely entails their possession of a gastrointestinal tract conforming to the foregoing quotation. It is generally contemplated that such nonhuman mammalian animals will largely be purchased from vendors thereof and that their “health” will be in consistent with the experimental uses for which they are sold. Accordingly, it is sufficient for the scope of the claims herein that a “normal” gastrointestinal tract simply not be grossly diseased, and this would be apparent if the foregoing quoted gastrointestinal anatomical landmarks and regions were not present in a nonhuman mammalian animal undergoing the surgical modification productive of the animal model claimed herein.

#### **REMARKS RESPONSIVE TO 35 U.S.C. § 102(b) REJECTIONS**

The Examiner rejected Claims 1, 2, 4, 5, 7, 8 under 35 U.S.C. § 102(b) as being allegedly anticipated by Young et al., 1984, The American Journal of Clinical Nutrition, 40. 293-302 (hereinafter “Young, et al.”), under the doctrine of inherency.

Applicant had, on page 17, 1<sup>st</sup> paragraph of his Reply to the Examiner’s First Office

Action stated that:

"Young et al. teach the elimination of the stomach as an organ of digestion, and since a functioning stomach is the very source of ghrelin production, (and) a reduction in ghrelin levels in postoperative rats could not possibly be inherent in Young, et al."

In her Final Office action, the Examiner noted that:

“With regards to this argument, it appears that the Applicant is supporting the Examiner's assertion that the levels of ghrelin in the rats taught by Young et al. would go down because these rats, which have no functional stomach (i.e., the stomach was eliminated), would also not express ghrelin.” [DETAILED ACTION: PAGE 7, MID-PARAGRAPH]

Applicant agrees with that portion of the Examiner's quoted statement indicating that the rats as surgically modified by Young, et al., had “no functional stomach (i.e., the stomach was eliminated).” Applicant has accordingly amended the Original Specification and Claims to limit the claimed surgical modification to a nonhuman mammalian animal to one in which the claimed surgical modification reduces (but does not eliminate) the volume of a functional stomach into which food enters and in which food is lodged while undergoing digestion in the stomach.

#### **REQUEST FOR EXTENSION OF TIME**

The Applicant herewith petitions the Commissioner of Patents and Trademarks to extend the time for reply to the Final Office Action mailed January 13, 2006 for two months. Submitted herewith is a check for \$225.00 to cover the cost of the extension.

If any additional fees, including additional extension of time fees, are due as a result of this response, please charge Deposit Account No. 503033.

This submission of a fee and authorization to charge Deposit Account No. 503033 is intended to act as a constructive petition for an additional extension of time, should an additional extension of time be needed as a result of this Response. Please credit any overpayment to the above referenced deposit account.

## CONCLUSION

In summary, as presently amended and based on the preceding remarks, Applicant respectfully believes that independent claim 1 and all claims dependent therefrom meet the acceptance criteria for allowance and therefore, upon the Examiner's reconsideration, requests allowance.

The Examiner is invited to telephone the undersigned if this would in any way advance the prosecution of this case. If the Examiner believes that anything further would in any way advance the prosecution of this case or be helpful to place the application in condition for allowance, the Examiner is invited to contact applicant's attorney at the telephone number listed below.

Respectfully submitted,

/Sander Rabin/

**Sander Rabin, MD JD**      May 19, 2006

Registration No. 53,498  
Customer No. 41672  
Convergent Technology Patent Law Group  
Whiteman Osterman & Hanna LLP  
One Commerce Plaza  
Albany, New York 12260  
srabin@woh.com  
(518) 487-7683